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| 10/615,383 | 07/09/2003 | Timothy J. Foster | P06335US03/BAS | 5842 |

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| EXAMINER | |
|---|---|
| ARCHIE, NINA | |
| **ART UNIT** | **PAPER NUMBER** |
| 1645 | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/615,383 | FOSTER ET AL. | |
| | Examiner | Art Unit | |
| | Nina A. Archie | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *18-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/19/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## *DETAILED ACTION*

1. This Office is responsive to Applicant's amendment and response filed 11-12-09. Claims 18-23 are pending and under examination. Claims 18-19 have been amended. Claims 2-10 and 13-17 have been cancelled. Claims 20-23 are new.

### *Objections/Rejections Withdrawn*

2. In view of the Applicant's amendments and remarks the following objections/rejections are withdrawn.

a) Objection to claim 4 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn in light of cancellation of the claim.

b) The rejections of claim 3 rendered vague and indefinite by the use of the term "recognizes" under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of applicant's amendment thereto.

c) The rejections of claims 9 and 16-17 that invoked 35 U.S.C. 112 6$^{th}$ paragraph, which is under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of cancellation of the claims.

d) The rejection of claim 18 for reciting the limitation "region" for lack of antecedent bases under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of applicant's amendment thereto.

e) The rejection of claims 2-5, 7-10, and 13-19 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of cancellation of the claims (2-5, 7-10, and 13-18) and in light of applicant's amendment thereto.

### *Information Disclosure Statement*

3. The information disclosure statements filed on 10/19/2009 has been considered. An initialed copy is enclosed.

***Claim Rejections Maintained***

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 18-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Doucette-Stamm et al. US Patent No. 6,380,370 Date August 13, 1998 for the reasons set forth in the previous Office Action in the rejection of claims 18-23.

**Applicant arguments**:

Applicants arguments filed in response to the 35 U.S.C. 102 (b) on November 12, 2009 is carefully considered, but not found to be persuasive for the reasons below.

Applicant argues that the Examiner only alleged that a "protein" was used to raise antibodies, and not particular portions of the full protein as the present claims. Applicants state that Doucette-Stamm is only directed to a disclosure of predicted nucleic acid and amino acid sequences, and refers to certain proteins that appear to be encoded by those sequences and that the reference at most discloses whole proteins. Applicant argues that Doucette-Stamm does not disclose or suggest the A domain of the SdrG protein recognized by the antibodies of the present claims and Doucette-Stamm does not have any disclosure or suggestion of specific portions of such proteins, such as the A domain, or any particular region within a sequence. Applicants state Doucette-Stamm does not anticipate or make obvious the present claims. Applicants state that assuming arguendo, that any proteins were actually expressed and antibodies were raised thereto, on the other hand there is no disclosure whatsoever of antibodies to a specific region or portion within a complete protein. Applicants argue there is no disclosure or suggestion that the actual protein may have been an extracellular matrix protein, and the lack of such information would make it impossible for one to have predicted or deduced any particular regions from the sequenced proteins and polypeptides. Applicants argue the disclosures of the polypeptide

sequences in the cited references do not disclose or make obvious the present claims which are directed to antibodies capable of binding to a sequence consisting of amino acids 51-598 of SEQ ID NO: 10 and the region, also known as the A domain, is nowhere disclosed or suggested in the cited prior art references, much less the generation of antibodies that are capable of recognizing this specific region.

**Examiner's Response to Applicant's Arguments:**

In response to Applicants statement as set forth supra, the claims are drawn to an isolated an antibody that binds to the ligand binding A region of an SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis wherein said region is encoded by the nucleic acid consisting of nucleotides 252 to 1895 of SEQ ID NO: 7; an isolated antibody capable of binding to an amino acid sequence consisting of amino acids 51 to 598 of SEQ ID NO: 10. As a result of the claims are specifically drawn to an antibody and limited to the ligand binding A region of an SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis wherein said region is encoded by the nucleic acid consisting of nucleotides 252 to 1895 of SEQ ID NO: 7 nor are the claims specifically limited to an amino acid sequence consisting of amino acids 51 to 598 of SEQ ID NO: 10.

Moreover, the specification discloses the in the A region of SdrF and SdrG there is a highly conserved amino acid sequence that can be used to derive a consensus TYTFTDYVD (SEQ ID NO:16) motif (see pg. 5 Figure 4) and that any combination of the variable sequence motif derived from the Sdr protein family, (T) (Y) (T) (F) (T) (D/N) (Y) (V) (D), can be used to impart immunity or to induce protective antibodies (see pg. 11).

Consequently, Doucette-Stamm et al. disclose a *Staphylococcus epidermidis* fibrinogen nucleic acid that encodes a protein that encompasses the claimed fragment of SEQ ID NO: 7 (see STIC results attached). Doucette-Stamm et al. further disclose a *Staphylococcus epidermidis* fibrinogen protein that encompasses the claimed fragment of SEQ ID NO: 10 (see STIC results attached). Moreover, the specification discloses the in the A region of SdrF and SdrG there is a highly conserved amino acid sequence that can be used to derive a consensus TYTFTDYVD (SEQ ID NO:16) motif (see pg. 5 Figure 4) and that any combination of the variable sequence motif derived from the Sdr protein family, (T) (Y) (T) (F) (T) (D/N) (Y) (V) (D), can be used to impart immunity or to induce protective antibodies (see pg. 11). Doucette-Stamm et al. teach a

*Staphylococcus epidermidis* fibrinogen protein encompassing the consensus sequence amino acid of SEQ ID NO: 16 TYTFTDYVD (see STIC results attached). Therefore, the claimed fragments of SEQ ID NOs: 7 and 10 encompassed by said protein of Doucette-Stamm et al. would necessarily induce antibodies that would necessarily bind to immunoepitopes present in both the recited fragments of SEQ ID NO:7 and SEQ ID NO:10 and the protein disclosed by Doucette-Stamm et al. Moreover, Doucette-Stamm et al. disclose that said protein was used to raise antibodies (see abstract, column 9, column 22 lines 25-40), column 25 lines 10-20, column 27 lines 10-17, column 41 lines 1-55). Therefore the isolated "protein" of Doucette-Stamm et al. was used to raise antibodies and anticipates all the limitations of the instant claims, hence Applicants response is unpersuasive.

In response to applicant's argument that the reference Doucette-Stamm et al. fail to show certain features of Applicants invention, it is noted that the features upon which applicant relies (i.e., the protein may have been an extracellular matrix protein, and the lack of information from Doucette-Stamm et al. would make it impossible for one to have predicted or deduced any particular regions from the sequenced proteins and polypeptides) are not recited in the rejected claim(s). See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Moreover, the claims are not specifically limited to a protein that may have been an extracellular matrix protein. Therefore the rejection is maintained.

As outlined previously, the claims are drawn to an isolated an antibody that binds to the ligand binding A region of an SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis wherein said region is encoded by the nucleic acid consisting of nucleotides 252 to 1895 of SEQ ID NO:7 (claim 18), an isolated antibody capable of binding to an amino acid sequence consisting of amino acids 51 to 598 of SEQ ID NO: 10 (clam 19), wherein the antibody is raised against the ligand binding A region of the SdrG fibrinogen-binding protein from coagulase-negative *Staphylococcus epidermidis* (claim 20), the isolated antibody that recognizes the ligand binding A region of the SdrG fibrinogen-binding protein from coagulase-negative *Staphylococcus epidermidis* (claim 21), a diagnostic kit for an antigen comprising the antibody and a means for identifying binding by said antibody to an antigen in a sample (claim 22), the isolated antisera containing the antibody (claim 23).

Doucette-Stamm et al. disclose a *Staphylococcus epidermidis* fibrinogen nucleic acid that encodes a protein that encompasses the claimed fragment of SEQ ID NO: 7 of amino acids 252-1895 (see STIC results attached). Doucette-Stamm et al. further disclose a *Staphylococcus epidermidis* fibrinogen protein that encompasses the claimed fragment of SEQ ID NO: 10 of amino acids 51-598 (see STIC results attached). Moreover, the specification discloses the in the A region of SdrF and SdrG there is a highly conserved amino acid sequence that can be used to derive a consensus TYTFTDYVD (SEQ ID NO:16) motif (see pg. 5 Figure 4) and that any combination of the variable sequence motif derived from the Sdr protein family, (T) (Y) (T) (F) (T) (D/N) (Y) (V) (D), can be used to impart immunity or to induce protective antibodies (see pg. 11). Doucette-Stamm et al. teach a *Staphylococcus epidermidis* fibrinogen protein encompassing the consensus sequence amino acid of SEQ ID NO: 16 TYTFTDYVD (see STIC results attached). Therefore, the claimed fragments of SEQ ID NOs: 7 and 10 encompassed by said protein of Doucette-Stamm et al. would necessarily disclose antibodies that would necessarily bind to shared immunoepitopes, hence Doucette-Stamm et al. disclose that said protein was used to raise antibodies (see abstract, column 9, column 22 lines 25-40), column 25 lines 10-20, column 27 lines 10-17, column 41 lines 1-55). Therefore the isolated "protein" of Doucette-Stamm et al. was used to raise antibodies and anticipates all the limitations of the instant claims. Consequently, Doucette-Stamm et al. anticipates all the limitations of the instant claims.

***New Grounds of Rejections***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 18, 20-21, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) As to dependent claim 21 is rendered vague and indefinite by the use of the term "recognizes" since it is not explicitly defined in the specification. "Recognizes" has no art defined meaning with respect to an antibody. Therefore, the skilled artisan would not be readily apprised of the metes and bounds of "recognizes" nor how to assess such. It is unclear how to interpret what is considered "recognizes" and inasmuch as it is not a recognized term and not defined in the specification.

b) As to dependent claim 25, states "a diagnostic kit comprising the antibody and a means for identifying binding by said antibody" that invokes 35 U.S.C. 112 6th paragraph. However the written description fails to clearly link or associate the disclosed structure, material, or acts to the claimed function such that one of ordinary skill in the art would recognize what structure, material or acts perform the claimed function.

Applicant is required to: (a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or (b) Amend the written description of the specification such that it clearly links or associates the corresponding structure, material, or acts to the claimed function without introducing any new matter (35 U.S.C. 132(a)); or (c) State on the record where the corresponding structure, material, or acts are set forth in the written description of the specification that perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP 2181 and 608.01(o).

6. Furthermore, it is stated that in response to applicant's arguments on 11/12/2009 in the previous office action on 5/12/2009 in regards to 5c) as set forth supra, whereby Applicants state "diagnostic kits are well known and understood in the art, and that anyone in this field would instantly understand what means for identifying binding would be." Applicants have not shown in the specification the sufficient structure, material, or acts of claim limitation "means for identifying binding for said antibody". Moreover, the information regarding diagnostic kits provided at pages 39-40 does not provide of the specification sufficient structure, material, or acts of claim limitation "means for identifying binding for said antibody".

Therefore, the instant rejection as set forth supra further addresses applicants arguments on 5/12/2009 in regards 5c) as set forth supra.

***Conclusion***

7. No claims are allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nina A Archie

Examiner
GAU 1645
REM 3B31

/Robert A. Zeman/
for Nina Archie, Examiner of Art Unit 1645